

**REMARKS**

With entry of this Amendment, claims 10-13, 16-18, 26-36 and 45-49 are pending under examination. Claims 2-4, 6-8, 15, 19-25, and 37-34 were previously withdrawn in response to a Restriction Requirement. By this Amendment, claim 17 has been amended to correct a grammatical error in accordance with the Examiner's suggestion.

Patentability Under 35 USC § 102(e)

Claims 26, 29-33, 35-36, 45, and 47-49 are rejected under 35 USC § 102(e) as allegedly anticipated by Dietrich et al. (US 2004/0058896 A1).

Dietrich et al. is relied upon for allegedly teaching:

a pharmaceutical preparation comprising an active (including bicipadine hydrochloride) and 1-25% of a polymer including HPMC

Applicants respectfully traverse the foregoing rejection and submit that the disclosure of Dietrich et al. neither teaches nor suggests the instantly claimed invention.

Dietrich et al. clearly fail to describe and enable the instantly claimed subject matter as required for a valid prior art reference cited under 35 USC § 102. Contrary to the Office's construction, Dietrich et al. merely lists hypothetical combinations of active agents and polymer ingredients, and does not actually provide pharmaceutical preparations with known ingredients, much less known pharmacologic and pharmacokinetic properties, that can be used by the public.

The purely prophetic content of the Dietrich et al. disclosure purports to cover such a vast range of compounds, it's current construction by the Office would preclude patenting of literally billions of prospective drug formulation inventions. It is axiomatic that the Dietrich et al. disclosure would not reasonably be construed by skilled artisans as actually placing these myriad possible formulations into the hands of the public.

Dietrich et al. purports to teach formulations for scores of different, fundamentally distinct classes of drugs, just covering the different drug classes that begin with the letter "A" (¶¶ [14]-[43], there are following major drug classes contemplated:

Adrenergics: Adrenocorticosteroids: Agents to prevent alcohol abuse: Aldosterone antagonists: Amino acids: Active ingredients

for ammonium detoxification: Anabolics: Analeptics: Analgesics:  
 Androgens: Anesthetic additives: Anesthetics (non-inhalation):  
 Anesthetics (local): Appetite suppressants: Anthelmintics: Acne  
 therapeutics:

Within each of the prophetic drug classes that Dietrich et al. purports to cover, there are typically scores of distinct drugs, also differing fundamentally in their structure, pharmacology, and physicochemical properties. For example, in the group of “Anesthetics (local)” (Applicants note for the record that bicifadine is *not* classified as a local anesthetic), the following laundry list of species is contemplated:

[0030] acetaminophen; alfentanil; aminobenzoate; aminobenzoate;  
 anidoxime; anileridine; anileridine; anilopam; anirolac; antipyrine;  
 aspirin; benoxaprofen; benzydamine; bicifadine hydrochloride;  
 brifentanil; brom adoline; bromfenac; buprenorphine; butacetrn;  
 butixirate; butorphanol; butorphanol; carbamazepine; carbaspirin  
 calcium; carbiphen; carfentanil; ciprofadol succinate; cirmadol;  
 cirmadol; clonixeril; clonixin; codeine; codeine phosphate;  
 codeine sulfate; conorphone; cyclazocine; dexodrol;  
 dexpemadol; dezocine; diflunisal; dihydrocodeine; dimefadane;  
 dipyrone; doxipicomine; drinidine; enadoline; epirizole; ergo  
 tamine tartrate; ethoxazene; etofenamate; eugenol; fenoprofen;  
 fenoprofen calcium; fentanyl citrate; floctafenine; flufenisal;  
 flunixin; flunixin meglumine; flupirtine; fluproquazone;  
 fluradoline; flurbiprofen; hydr omorphone; ibufenac; indoprofen;  
 ketazocine; ketorfanol; ketorolac; letimide; levomethadyl acetate;  
 levomethadyl acetate hydrochloride; levonantradol; levorphanol;  
 lofemizole; lofentanil oxalate; lorcinadol; lomoxicarn; magnesium  
 salicylate; mefenamic add; menabitan; meperidine; meptazinol;  
 methadone; methadyl acetate; methopholine; methotrimeprazine;  
 metkephamid acetate; mimbane; mirfentanil; molinazone;  
 morphine sulfate; moxazocine; nabitan; nalbuphine; nalmexone;  
 namoxyrate; nantradol; naproxen; naproxen; naproxol; nefopam;  
 nexeridine; noracymethadol; ocfentanil; octazamide; olvanil;  
 oxetorone; oxycodone; oxycodone; oxycodone terephthalate;  
 oxymorphone; pemedolac; pentamorphone; pentazocine;  
 pentazocine; phenazopyridine; phenyramidol; picenadol;  
 pinadoline; pifenidone; piroxicam olamine; pravadoline;  
 prodilidine; profadol; propiram; propoxyphene; propoxyphene  
 napsilate; proxazole; proxorphan; pyrroliphen; remifentanil;  
 salcolex; saletamide maleate; salicylamide; salicylate meglumine;  
 salsalate; salicylate; spiradoline; sufentanil; sufentanil; talmetacin;  
 talniflumate; talosalate; tazadolene; tebufelone; tetradamine;

tifurac; tilidine; tiopinac; tonazocine; tramadol; trefentanil;  
trolamine; veradoline; verilopam; volazocine; xorphanol; xylazine;  
zenazocine mesilate; zomepirac; sucapsaicin.

Nowhere does Dietrich et al. even attempt to distinguish properties among these major drug classes and groups of species that would ordinarily be considered critical when developing specific drug formulations.

Whenever the Patent Office relies upon an allegedly anticipatory reference to support a rejection under 35 U.S.C. § 102, the Office bears the initial burden of demonstrating that the reference all of the elements and limitations of the claimed invention.

The factual determination of anticipation requires the disclosure in a single reference of every element of the claimed invention ... It is incumbent upon the examiner to identify therein each and every face to the claimed invention is disclosed in the applied reference.

Ex Parte Levy, 17 USPQ2d, 1461, 1462 (Bd.Pat.App.Int. 1990) (citations omitted).

Moreover, a reference cited as anticipatory must fulfill, *inter alia*, all of the written description and enablement requirements of 35 U.S.C. § 112 Supra.

Electronulceonics.

[E]ven if the claimed invention is disclosed in a printed publication, that disclosure will not suffice as prior art if it was not enabling.

In re Donohue, 226 USPQ 619, (Fed. Cir. 1985) (citing In re Borst, 45 USPQ 544, 557 (CCPA 1965), cert. den. 382 U.S. 973, 148 USPQ 771 (1966)

Mere recitation of lists of hundreds or thousands of compounds cannot serve as an anticipatory reference to deny patent protection for such compounds to those who actually discover them later.

E.I. du Pont de Nemours and Co. v. Ladd, Comr Pats., 140 USPQ 297, 302 (D.C. Cir. 1964).

As further explained by the Federal Circuit in In re Donohue, 226 USPQ 619, 621 (Fed. Cir. 1985):

It is well settled that prior art under 35 U.S.C. § 102 (b) must sufficiently describe the claimed invention to have placed the public in possession of it. (emphasis added).

In view of the foregoing facts and authority, the record is clear that Dietrich et al. fail to describe or enable the instantly claimed invention. Accordingly, withdrawal of the rejection of claims 26, 29-33, 35-36, 45, and 47-49 under 35 USC § 102(e) is earnestly solicited.

Patentability Under 35 USC § 103

Claims 10-13, 16-18, 26-36, and 45-49 are rejected under 35 USC § 103(a) as allegedly unpatentable over Fanshawe et al.(US 4,231,935) in view of Dietrich (US 2004/0058896A1).

Fanshawe et al. is relied upon for allegedly disclosing:

substituted 3-azabicyclohexanes including bicifadine, the azabicyclohexanes could be formulated into oral dosage forms such as tablets containing between 10 to 400 mg of the active and binders such as dicalcium phosphate (a calcium phosphate). See col 20 lin 42-col 21 lin 16 and example 36. Regarding claim 17 Fanshawe discloses that the active can comprise anywhere between about 5% to 75% or more of the weight of the dosage form, it is therefore obvious that the rest of the dosage form would comprise the other excipients including the binder, therefore the skilled artisan could through routine experimentation form the disclosed percentages come up with the same amount of carrier as applicants currently claimed invention.

Dietrich et al. is cited as above, as a secondary reference, for allegedly teaching “that oral dosage forms containing analgesics such as bicifadine hydrochloride and HPMC was already well known in the art at the time of the invention.”

Applicants respectfully traverse the foregoing rejection and submit that the references by Fanshawe et al., and Dietrich et al., viewed for what they disclose in combination, neither teaches nor suggests the instantly claimed invention.

The Office’s reliance on Fanshawe et al. is limited to the disclosure by this reference of a class of substituted 3-azabicyclohexanes that includes bicifadine, and the alleged teaching that these varied compounds can be formulated with “binders” and “other excipients” in general percentages. Because Fanshawe et al. is not cited as an

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allegedly anticipatory reference, it is clear that the Office recognizes that Fanshaw et al. fail to teach the instantly claimed invention. Accordingly, the Office appears to rely solely on Dietrich et al. for allegedly teaching that “oral dosage forms containing analgesics such as bicipadine hydrochloride and HPMC was already well known in the art,”

According to the Office’s construction of Dietrich et al., discussed above, it would allegedly be obvious to formulate ANY and ALL analgesics (in fact, ANY and ALL compounds from the vast groups and species contemplated by Dietrich et al.), in a sustained release formulation as presently claimed by Applicants for the specific and distinct drug, bicipadine. Prior to further examination of this application, Applicants respectfully urge the Office to either specifically ratify or reject this construction. If the construction is ratified, it would, in Applicants’ view, contravene fundamental policies and precepts of the US Patent Act, effectively foreclosing patenting of novel, sustained release formulations for virtually all drugs.

In the instant case, the burden falls upon the Office to specifically identify a suggestion, or “practical” motivation in the art to formulate bicipadine in a sustained release, oral dosage form as provided by Applicants, with an expectation that such formulation would have similar properties and beneficial characteristics as described in Applicants’ specification.

The record in this case contravenes such a suggestion or motivation, because bicipadine was known as an analgesic for treating acute pain. Those skilled in the art at the time of the invention would not have been motivated to formulate bicipadine in a sustained release, oral dosage form. On the contrary, the art of record teaches away from this direction, because one seeking to formulate an acute pain drug such as bicipadine would seek to deliver the drug rapidly to achieve fast onset of acute pain relief. Accordingly, various distinct dosage forms would have been selected as opposed to the instant, sustained release, dosage form. In particular, the artisan would have been strongly motivated to select an “immediate release” IR, dosage form, consistent with the teachings and knowledge in the art relating to bicipadine.

Neither disclosure of Fanshaw et al., nor of Dietrich et al., teach any specific attributes of bicipadine, either pharmacological, physicochemical, or pharmacokinetic,

that would have provided alternate motivation or direction, and thus the record fails to evince that a sustained release formulation of bicifadine would have been obvious. Again, the Office must point to a specific teaching or suggestion in the cited art that would have led to the claimed invention, and the disclosure of Dietrich et al., relied upon exclusively for alleged formulation details, would have to be construed to cover virtually all known drugs in order to support the Office's position. Such construction would be tantamount to a position that specific drug properties (pharmacological, physicochemical, or pharmacokinetic), have no bearing on drug formulation investigation and development, and that the art of drug formulation investigation and development itself is devoid of any prospective inventive contribution.

In view of the foregoing, Applicants respectfully request that the rejection of claims 10-13, 16-18, 26-36, and 45-49 under 35 USC § 103(a) as allegedly unpatentable over Fanshawe et al. in view of Dietrich et al. be withdrawn.

### CONCLUSION

Applicants respectfully submit that all claims pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes that a telephone conference would expedite prosecution of this application, please telephone the undersigned at (206) 381-3300.

Date: August 1, 2007

Respectfully submitted,



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